

Exhibit 2

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

MDL NO. 2804

CASE NO. 17-md-2804

Hon. Dan A. Polster

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

TRACK THREE CASES

VOLUME I

REMOTE VIDEO DEPOSITION OF

JAMES RAFALSKI

(CONTAINS TESTIMONY DESIGNATED HIGHLY CONFIDENTIAL)

June 10, 2021

REPORTED BY: Laura H. Nichols

Certified Realtime Reporter,

Registered Professional

Reporter and Notary Public

1 yes, sir.

2 Q. And incidental to that business, they
3 have at some point in time, at least some them, had
4 warehouses that they distributed some of the drugs
5 that they sold to their own pharmacies, correct?

6 A. Yes. I would agree with that,
7 Mr. Livingston.

8 Q. They did not distribute any drugs to
9 any pharmacies other than their own?

10 A. That is a correct statement.

11 Q. And there are other defendants in
12 this case who were pure distributors, meaning that
13 they distributed to all kinds of customers who were
14 not a part of their own businesses, correct? For
15 example, McKesson, Cardinal, AmerisourceBergen,
16 correct?

17 A. If you mean that they did not own,
18 self-own the pharmacies they were distributing to,
19 yes, I would agree with that.

20 Q. They were third-party distributors,
21 correct?

22 A. I don't know that I would call them
23 third-party. They are just distributors, and they
24 are a standalone, and they don't distribute to
25 their own entities, other than for -- to each of

1 distributor, correct?

2 A. I have not.

3 Q. But you have offered opinions about
4 distribution, correct?

5 A. Well, I shut down distributors also
6 in my employment.

7 Q. Yeah, right. And you have offered
8 opinions in these various opioid cases about the
9 conduct of distributors, including the defendant
10 pharmacies in this case, correct?

11 A. Yeah, that is a correct statement.
12 Just clarification --

13 Q. Okay. So a lack of --

14 MS. KNIGHT: Scott -- Scott --

15 Q. (BY MR. LIVINGSTON:) The fact that
16 you were never a distributor did not prevent you
17 from offering an opinion about distribution,
18 correct?

19 MS. KNIGHT: Mr. Livingston, you have
20 got to let him finish answering his questions. You
21 don't get to cut him off.

22 A. Just to finish the -- when I was
23 answering, I have not been asked to provide an
24 opinion in regards to a pharmacy. So I didn't
25 conduct that analysis or do any research or review

1 any records to formulate an opinion related at a
2 pharmacy level, and I was not asked to do that.

3 I only provided opinions on the
4 distributors, and that is because that is what I
5 was asked to do.

6 Q. (BY MR. LIVINGSTON:) That is what I
7 suspected. So you could have provided an opinion
8 about the pharmacy -- the defendant pharmacies'
9 conduct as pharmacies, but you were not asked to do
10 that and, therefore, you did not do that, correct?

11 A. That is a correct statement.

12 Q. Now, so far in all of the opioids
13 cases in which you have offered any opinions and
14 ultimately some testimony, you have always
15 concluded that every suspicious order monitoring
16 system that you examined was -- did not comply with
17 the applicable DEA regulations; is that correct?

18 A. Generally speaking, I would answer
19 yes. I think I may have provided testimony that
20 there were certain time periods later -- later in
21 the time frames that I reviewed that they had
22 systems that had the potential to be effective
23 systems.

24 Q. And we are talking at this point
25 fifteen, twenty defendants whose distribution

1 activities you have offered opinions about; is that
2 in the ballpark?

3 A. Yes, I think that would be -- that
4 would be potentially accurate, yes, sir.

5 Q. Okay. So, so far the defendants are
6 batting zero with you; is that fair to say?

7 MS. KNIGHT: Object to form.

8 A. Yes, sir, that would be an accurate
9 statement.

10 Q. (BY MR. LIVINGSTON:) Okay. Given --
11 you are aware that we are still in the midst of an
12 opioids crisis, correct?

13 A. I would agree, yes, sir.

14 Q. Given that you have concluded that,
15 in your view, all of these various defendants, many
16 of whom are still operating today, do not have
17 systems that comply with DEA regulations, have you
18 reported them to the DEA? Have you called any of
19 your old colleagues up and said you might want to
20 examine so and so and take a quick look at, you
21 know, this company or that company?

22 A. I have not, Mr. Livingston.

23 Q. Now, do you know Dr. McCann?

24 A. I do.

25 Q. And you have worked with him to some

1 inspections had not identified any issue.

2 Q. (BY MR. LIVINGSTON:) And -- yeah,
3 I'm not talking about situations where, you know,
4 the registrant tells you, here's our system, but
5 they don't actually follow their system. They
6 don't actually operate it the way they tell you.

7 I'm just talking -- assuming that the
8 registrant actually operates the system in the
9 manner in which they've described it to you. And
10 you say, sounds good to me, shouldn't the
11 registrant -- and as a matter of all fairness -- be
12 able to rely on that representation that they're
13 fine?

14 MS. KNIGHT: Objection to form.

15 A. I don't fully disagree with what
16 you're saying. But I'd have to say that a
17 registrant is bound to comply with the regulations,
18 and that's not dependent on whether or not an
19 inspection is conducted, and an issue is not found
20 or discovered or detailed by a diversion
21 investigation, it doesn't relinquish the
22 responsibilities to comply with the regulations.

23 Q. (BY MR. LIVINGSTON:) Oh, no. Of
24 course, the law is the law. The question is
25 whether they can rely, in all fairness, on what

1 you're telling them as an expert. Right? These
2 are DEA regulations. You're a DEA investigator
3 whose job it is to enforce those regulations.
4 Nobody knows those regulations, presumably, when
5 you're on the job, any better than you, and you're
6 coming in to a registrant and you're telling them
7 that they're okay, shouldn't they be able to rely
8 on that?

9 MS. KNIGHT: Objection to form.

10 A. As I answered earlier, I generally
11 agree with that. But there are certain areas that
12 a registrant should -- would seek a higher
13 approval.

14 Q. (BY MR. LIVINGSTON:) Let's now --
15 I'd like to just give me a little road map here.
16 Let's now focus on the DEA regulations that you've
17 described in some detail so far this morning.

18 Let's -- to do that, let's --

19 MS. KNIGHT: Mr. Livingston, if we're
20 switching gears, can we just take a quick
21 five-minute comfort break? Is this --

22 MR. LIVINGSTON: Sure.

23 MS. KNIGHT: Okay. Real quick.

24 THE VIDEOGRAPHER: The time is now
25 approximately 9:18 a.m. We're off the record.

1 you asked me earlier.

2 Q. So the answer is no?

3 A. That's correct. The answer is no.

4 Q. Okay. And remember when we were
5 talking before about the various levels of
6 enforcement that were available to you as a DEA
7 inspector, if a registrant was not in compliance
8 with the regulations? Do you remember when we
9 talked about that a minute ago?

10 A. Yes. Available to the agency, not to
11 me specifically. But, yes, I remember the
12 conversation.

13 Q. Right.

14 When you inspected distributors while
15 you were with the DEA, how often did you conclude
16 that they were in full compliance with all
17 applicable DEA regulations? Roughly, percentage,
18 you know, ten percent, sixty percent, a hundred
19 percent, ninety percent, whatever it is.

20 MS. KNIGHT: Objection to form.

21 A. Are you -- in regards to your
22 question, was that specific to distributors?

23 Q. (BY MR. LIVINGSTON:) Yes.

24 A. I think generally speaking, off the
25 top of my head, distributors -- there's a large

1 volume of regulations. So I would say that there
2 was generally at least maybe fifty percent, maybe a
3 little less of time where there would be some kind
4 of violation.

5 Q. Okay. All right. Would you turn to
6 Exhibit 6, Page 9? Giant Eagle Exhibit 6.

7 (GE Exhibit 6 was marked for
8 identification.)

9 Q. (BY MR. LIVINGSTON:) And the pages
10 are at the top. See, this is Section 1301.71 of
11 the DEA's Controlled Substance Act regulations?

12 MS. KNIGHT: Mr. Livingston, that's
13 not what's behind his tab.

14 A. 6? You said 6?

15 Q. (BY MR. LIVINGSTON:) Yes.

16 A. Tab 6 I have "Linden Barber" --

17 Q. Yeah. No. It -- yeah, but just go
18 to the Page 9 at the top. It's a compilation of
19 various -- yeah. Yeah. It was a trick question.
20 Sorry about that.

21 A. No. I didn't hear the "Page 9." I'm
22 sorry.

23 Okay. I'm there.

24 Q. Yeah. You're familiar with this
25 regulation, correct?

1 A. Yes, sir.

2 Q. Okay. And when you would inspect
3 registrants, you would try to make sure that they
4 were complying with 1301.71, correct?

5 A. Among many other regulations, yes.

6 Q. I didn't mean it to be exclusive.
7 But among -- that you would make sure they were in
8 compliance at least with 1301.71?

9 A. Yes.

10 Q. And this regulation says, "All
11 applicants and registrants shall provide effective
12 controls and procedures to guard against theft and
13 diversion of controlled substances."

14 That is one of the regulations that
15 you believe the defendants did not comply with in
16 this case, correct?

17 A. That's correct.

18 Q. Now, the next sentence says, "In
19 order to determine whether a registrant has
20 provided effective controls against diversion, the
21 administrator" -- that's really the DEA, right --
22 "shall use the security requirements set forth in
23 Sections 1301.72 through 1301.76," correct?

24 A. Yes.

25 Q. Okay. So if we want to know whether

1 the defendants are complying with this overarching
2 requirement for having effective controls, the DEA
3 says we're supposed to look at the -- all the
4 regulations between 72 and 76, correct?

5 A. That's what this says, yes, sir.

6 Q. Yeah. And that's what you did when
7 you were a DEA investigator, correct?

8 A. It's one of the things I did, yes,
9 sir.

10 Q. Okay. And the SOM regulation is one
11 of the regulations, but just one of the regulations
12 between 1301.72 and 1301.76, correct?

13 A. That's correct.

14 Q. And then if we skip down to
15 1301.71(b), it says, "Substantial compliance with
16 the standards set forth in Sections 1301.72 to
17 1301.76 may be deemed sufficient by the
18 administrator after evaluation of the overall
19 security needs -- or system -- overall security
20 system and needs of the applicant or registrant."

21 Do you see that?

22 A. Yes, sir.

23 Q. What does "substantial compliance"
24 mean?

25 A. Well, it -- the word "substantial"

1 would mean in compliance, substantial, more than
2 just trying. It would be substantial in
3 compliance.

4 Q. Well, doesn't it mean less -- at
5 least less than one hundred percent?

6 A. That may be your interpretation. I
7 think "substantial" would mean in compliance.

8 Q. Well, are you saying that your
9 definition of "substantial" is there has to be
10 perfect compliance?

11 A. I don't know that I'm saying there's
12 perfect. But I think you couldn't find any obvious
13 faults. It would be in compliance.

14 Q. Well, I mean, let's just assume that
15 you're -- you get -- you're in compliance with nine
16 out of ten or ten out of eleven. I mean, is that
17 substantial? Or do you have to have perfect
18 compliance? You can't be noncompliant with any
19 regulation to be "in substantial compliance with
20 the regulations"?

21 MS. KNIGHT: Objection to form.

22 A. I think substantial -- because if we
23 look down at the column of different items to be in
24 compliance with, they're broad and they give
25 various descriptions. So I think "substantial

1 compliance" would mean you can't find any faults of
2 noncompliance.

3 I'm not sure I would say it has to be
4 perfect. But if you were to find that there were
5 an obvious failure to be in compliance, that would
6 not be substantial.

7 I think substantial is more than just
8 average or trying. I think it shows a high level
9 attempt to be in compliance.

10 Q. (BY MR. LIVINGSTON:) Now, you're
11 very familiar with the SOM regulation, correct?

12 A. Yes, sir.

13 Q. And that regulation says that you
14 have to have a Suspicious Order Monitoring system
15 that's going to identify orders of unusual size,
16 pattern or frequency, correct?

17 A. Well, in the beginning it says, "You
18 must design and operate."

19 Q. Yeah. But the system is supposed to
20 be able to identify unusual orders from a size,
21 pattern and frequency perspective, correct?

22 A. But I don't -- yeah, it does say
23 that, but I don't believe that's an exclusive
24 statement. That doesn't say that's the only things
25 that it should identify. But I would agree it does

1 the quota is. Just that if the -- you've already
2 told me that you know that the quota is supposed to
3 be a forecast of the coming medical and research
4 demand for the drug, correct?

5 A. Yeah. But my answer is in regards to
6 your hypothetical, is you said some percentages and
7 some drug types and some expectations at a pharmacy
8 level. And I just don't have -- that's a pretty
9 broad question, hypothetical question.

10 It's -- the manufacturing is much
11 more complex. And to make it a specific drug at a
12 specific pharmacy, I just don't -- I don't think
13 that's an accurate hypothetical, and I just don't
14 have the expertise or the knowledge to answer that
15 or agree with that or disagree with that.

16 Q. Okay. And when you asked Dr. McCann
17 to run his methodologies, you did not ask him to
18 take into consideration what the annual increases
19 in the DEA quotas were for the drugs that he looked
20 at, correct?

21 A. That's a correct statement. I did
22 not do that.

23 Q. Let's try another hypothetical that's
24 a little -- hopefully a little easier.

25 Let's assume that a pharmacy -- and

1 let's say Giant Eagle. It's folks at the corporate
2 headquarters know that a pharmacy across the street
3 from one of its pharmacies in Lake County is
4 closing its doors. Its biggest competitor in the
5 area is closing its doors.

6 And they do an analysis and they say,
7 we think our prescriptions for controlled
8 substances are probably going to go up by twenty
9 percent because of that closure. And, in fact, the
10 scripts for that drug go up twenty percent or less.

11 You would agree that, from Giant
12 Eagle's perspective, that that increase was not
13 unexpected, correct?

14 MS. KNIGHT: Object to form.

15 A. That's another complex hypothetical.
16 Generally speaking, that could occur, but -- so
17 what we're talking about there, the essence would
18 be the Suspicious Order Monitoring system and due
19 diligence.

20 So my expectations is that there
21 would actually be some confirmation of that
22 happening, and some due diligence investigation.
23 But it could happen and I would agree with your
24 hypothetical.

25 Q. (BY MR. LIVINGSTON:) And you did not

1 your report in Exhibit 2? Do you see this is where
2 you say that the defendants' supposedly
3 noncompliant SOM systems, which you characterize as
4 sort of systemic failures, were a "Substantial
5 cause of the opioid epidemic plaguing the country
6 and specifically in Lake County and Trumbull
7 County"; do you see that?

8 A. Yes, sir.

9 Q. That is your opinion, correct?

10 A. It is.

11 Q. And what do you mean by substantial?

12 A. I mean it wasn't a close call. It
13 was obvious.

14 Q. Well, what about in comparison to
15 others that contributed to the opioid crisis in
16 these two counties?

17 A. What others are you speaking of,
18 Mr. Livingston?

19 Q. Well, we talked about it earlier.
20 You didn't analyze what the big three distributors'
21 contribution, if anything, was to the opioid crisis
22 in these counties, correct?

23 A. That's correct.

24 Q. You didn't look at any pill mill
25 doctors who were writing illegal scripts for

1 opioids in those two counties, did you?

2 A. That's correct.

3 Q. You didn't look at any independent
4 pharmacies who were ultimately shut down for
5 writing illegal scripts in these two counties,
6 correct?

7 A. That's correct.

8 Q. You didn't look at what the amount of
9 theft from medicine cabinets or what have you after
10 scripts were filled in -- legitimate scripts were
11 filled in those two counties for opioids, correct;
12 you didn't try to figure that out?

13 A. That is correct, Mr. Livingston,
14 because I wasn't asked to form an opinion on those
15 things.

16 Q. And you weren't asked to look at what
17 contribution, if any, manufacturers of opioids made
18 by any conduct that they were responsible for,
19 including their marketing efforts, correct?

20 A. Not contained within this specific
21 opinion, that is correct.

22 Q. And in order to contribute to the
23 opioid epidemic in these two counties, the
24 defendant pharmacies had to have had problems at
25 the pharmacy level, correct?

1 MS. KNIGHT: Objection to form.

2 A. I do not disagree with that
3 statement.

4 Q. (BY MR. LIVINGSTON:) Right. I mean
5 just, this is, I think, pretty simple logic that
6 your focus was entirely on the defendants' conduct
7 as distributors, correct?

8 A. In concert with the distribution to
9 their pharmacies, yes.

10 Q. And even if the defendants were, you
11 know, as you claim, not doing a good job of
12 complying with DEA regulations at the distribution
13 level, if their pharmacies were exemplary
14 pharmacies with respect to controls against
15 diversion, and their pharmacies were doing
16 everything that a good pharmacy should be doing, at
17 the end of the day, there's -- it doesn't matter,
18 because there's not going to be any diversion as a
19 result of what the pharmacies were doing at the
20 distribution level, correct?

21 MS. KNIGHT: Object to the form.

22 A. Well, in that hypothetical, because
23 of the failures of the company, and not doing due
24 diligence and not providing me with the information
25 to see that that was actually accurate, there's no

1 way that I could use that to formulate my opinion.

2 Q. (BY MR. LIVINGSTON:) No, we already
3 know -- we have already covered, you are not
4 offering the jury any opinions about the
5 defendants' conduct as pharmacies; you didn't look
6 at it, and it is not in your report, and you are
7 not going to testify about it.

8 I am just saying that, as a matter of
9 logic, unless the defendants were doing something
10 wrong at the pharmacy level -- if they were doing
11 everything they were supposed to be doing,
12 exercising their corresponding duty, they had good
13 controls against theft, you know, whatever you want
14 to dream up, come up with your dream pharmacy with
15 respect to anti-diversion measures, if that is the
16 case, then at the end of the day, it doesn't matter
17 what their warehouses are doing with respect to
18 compliance because those drugs are not going to end
19 up being diverted, correct?

20 MS. KNIGHT: Objection to form.

21 A. I don't agree with that hypothetical.
22 That is why the regulations are in place to
23 operate -- I mean to design and operate a SOMs.
24 And that is why there's due diligence in effect.
25 And I don't think -- if I understand your

1 hypothetical, you are saying that essentially, the
2 drugs don't need to be monitored if all of the
3 pharmacies are perfect.

4 And I don't think that is actually
5 what occurred in this case. So I just don't agree
6 with that hypothetical.

7 Q. (BY MR. LIVINGSTON:) You are
8 fighting my hypothetical. Let me make it even
9 simpler.

10 Okay. I am not suggesting that if
11 the pharmacies aren't complying with the
12 regulations that they are supposed to as
13 distributors, they can't get letters of
14 admonishment, get fined, get in trouble with the
15 DEA. I'm not saying that. I am just saying that
16 in terms of contributing to diversion in a
17 particular area, which is your opinion that you
18 have in your report on Page 7, that can't happen
19 and won't happen if, despite their noncompliance as
20 distributors, they are doing everything that a good
21 pharmacy is supposed to do and there is no
22 diversion going on at their pharmacies, correct?

23 MS. KNIGHT: Object to form.

24 A. Well, in regards to that
25 hypothetical, I guess before I comment on it, in a

1 perfect world, I don't think that your hypothetical
2 is possible. But in listening to your
3 hypothetical, if everything was absolutely perfect
4 with every pharmacy, then it is, hypothetically,
5 potentially it could be true.

6 Q. (BY MR. LIVINGSTON:) Now, when you
7 try to analyze whether a distributor is complaining
8 with the SOM regulation, you have to look at the
9 nature of the -- of the distributor's business,
10 correct? That is right in the regs, you are
11 supposed to take those sorts of things into
12 consideration?

13 A. Generally I agree with that, yes,
14 sir.

15 Q. And that is why the DEA -- you know,
16 there's no one-size-fits-all for SOM regulations,
17 correct?

18 A. I believe we touched on that earlier.
19 I believe that is why the regulation is good as it
20 stands, because it allows the ability for a
21 registrant to design their own system to meet their
22 own needs and their own customer base, and it is
23 fluid and allows them to change it. I don't think
24 there's a one-size-fits-all that could ever handle
25 the totality of distributor activities in there.

1 Q. Now, no matter how many times we look
2 at the DEA's some regulation, we won't find any of
3 the seven methodologies that you asked Mr. --
4 Dr. McCann to use when he crunched the data,
5 correct?

6 A. The DEA regulations never contained a
7 methodology or an algorithm.

8 Q. Okay. And, in fact, the DEA doesn't
9 even require that a registrant have an automated
10 threshold system. They can use a manual system if
11 they desire?

12 A. If they can -- if it can be designed
13 and operated and identify suspicious orders, yes,
14 sir.

15 Q. Okay. When you were inspecting
16 distributors, you know, while you were with the
17 DEA, did you ever recommend to any of them that
18 they use any of the methodologies that you are now
19 embracing in your report?

20 A. No, sir. It would have been improper
21 for me to do that. I think the farthest guidance,
22 probably the only guidance I can recall is there
23 was a period of time when the HDMA had a suspicious
24 order monitoring draft or a guide policy, and I
25 wouldn't direct a registrant to that, especially a

1 new registrant. But I may say that if they did
2 some Google research, they may get some good ideas
3 off the internet. But I never specifically
4 directed any registrant to any type of a suspicious
5 order monitoring system.

6 Q. Okay. Now, the results that
7 Dr. McCann came up varied greatly for each one of
8 the defendants under the methodologies that you
9 gave him to use, correct?

10 MS. KNIGHT: Object to form.

11 A. In your question, are you asking me
12 the results varied greatly?

13 Q. (BY MR. LIVINGSTON:) Yes, the
14 results.

15 A. Yes.

16 MR. LIVINGSTON: Let's go to
17 Exhibit -- Giant Eagle Exhibit 24.

18 (GE Exhibit 24 was marked for
19 identification.)

20 Q. (BY MR. LIVINGSTON:) This is a chart
21 that we had our version of a Dr. McCann put
22 together which is just really taking the results
23 from his report and your report for Giant Eagle.
24 This is a comparison of the methodologies for
25 flagging distribution orders, you know, seven

1 methodologies that you use. And here are the
2 numbers that were flagged for hydrocodone for Giant
3 Eagle's pharmacies in Lake County.

4 And do you see that, depending on
5 which flavor you pick, the numbers go anywhere from
6 zero percent to a hundred percent, correct?

7 A. I agree. I see that.

8 Q. Yeah. And that is -- I mean this is
9 an accurate comparison of the results that you
10 relied on, correct?

11 A. Well, if this is your expert that
12 prepared this --

13 Q. All they did was cut and paste it
14 from Dr. McCann. We can go back. Don't these
15 results look familiar to you?

16 A. I would have to go to the charts.
17 Not off the top of my head. I don't memorize them.
18 I'm not disputing you, but if you wanted, I would
19 have to compare them to his results. These are bar
20 graphs. I think mine are in actual percents and
21 numbers.

22 Q. Right. We wanted to make this a
23 little easier for the jury to see.

24 You would agree that if these numbers
25 are correct, that the error rate, depending on

1 A. Yes. But I am not sure how you are
2 drawing a correlation to the chart. But when I
3 look at this chart, just for informational
4 purposes, I do see an escalation of the dispensing
5 of hydrocodone by the Giant Eagle pharmacies,
6 leading up to 2012 when many declines occurred
7 throughout the industry. So that would be a
8 concern, the years of 2009, '10, 11, exceeding the
9 quota, comparison quota. So that also would be
10 alarming to me or would be of concern to me.

11 Q. What factors would you look at --
12 look for to try to determine whether you have a
13 good pharmacy or a bad pharmacy?

14 A. I would look at ordering patterns and
15 I would look at -- I would review prescribing
16 patterns, prescriber patterns. That would be a
17 preliminary.

18 Q. What about, you know, Oxy A, that is
19 a high dose form of oxycodone --

20 MS. KNIGHT: Let him finish.

21 A. I wasn't quite finished, sir, I am
22 sorry.

23 I would look at the types of drugs
24 that were dispensed in relation to all drugs. I
25 would look at all drugs compared to controlled

1 substances. I would look at cash and noncash
2 payments. I would look at the volume. I would
3 look at the geographic area. I would look at other
4 pharmacies nearby. I would look at a bunch of
5 different factors in helping to draw a conclusion
6 on that issue we are talking about.

7 Q. (BY MR. LIVINGSTON:) Okay. And I
8 think -- I already know the answer, but you didn't
9 look at any of these factors with respect to any of
10 the pharmacies in this case, correct?

11 A. I wasn't asked to provide an opinion
12 on pharmacies, so I did not.

13 Q. Yeah. No, I don't care why you
14 didn't. I just want to know whether you did or you
15 didn't. You did not, correct?

16 A. I said I did not.

17 MS. KNIGHT: Asked and answered.

18 A. I was not asked to.

19 Q. (BY MR. LIVINGSTON:) Now, controls,
20 one of the things you suggested was your percentage
21 of controls versus noncontrols, correct?

22 A. That's correct, sir.

23 Q. And I think SafeScript, didn't they
24 have like ninety percent controls?

25 A. Yes. But I don't know the exact

1 Q. All right. So essentially,
2 Mr. Crowley is asking you for some advice about
3 when he -- when he investigates a pharmacy, you
4 know, what he should look for as potentially signs
5 that, you know, there's a problem, correct?

6 A. Yes.

7 Q. And then you -- you provided him with
8 some guidance, correct?

9 A. Yes.

10 Q. And the first thing you say is you
11 would want to observe the pharmacy for a while.
12 You say, "I might also take some time and drive
13 around the surrounding area. Generally in Detroit
14 most of these problem pharmacies will have illegal
15 sales or transfer of pills from the purchaser to
16 someone outside. It is a fairly common activity."

17 I mean are you essentially saying you
18 want to be on the lookout for long lines of people
19 who are zombie-like or out-of-state licenses in the
20 parking lot of the pharmacy, that sort of thing?

21 A. Yeah, generally speaking. I don't
22 recall the names, but I recall the locations of a
23 couple of the pharmacies, and they were a
24 concerning area to go to in the city of Detroit.
25 So I am just giving him some general guidance about

1 MR. LIVINGSTON: Okay. We're almost
2 there.

3 Q. (BY MR. LIVINGSTON:) Now, you did
4 make this comparison with respect to Safe Script.
5 You looked at Safe Script's oxy dispensing compared
6 to what other pharmacies were doing, correct? You
7 specifically looked at that?

8 A. Yes, sir.

9 Q. Okay. That's the exercise we just
10 went through. We looked at how much some of the
11 independents were dispensing, all defendants,
12 nondefendants, Giant Eagle, right, we just went
13 through that exercise?

14 MS. KNIGHT: Objection to form.

15 A. Yes, but again, it's just one
16 specific drug for a broad timeline. So it's a very
17 limited picture of the activity of the pharmacy.

18 Q. (BY MR. LIVINGSTON:) Did you review
19 any of the testimony in this case that was provided
20 under oath by several Ohio Board of Pharmacy agents
21 who were responsible for Lake and Trumbull
22 Counties, did you look at that testimony?

23 A. No, sir. I did not.

24 Q. So you're not aware of the fact that
25 Agent Pavlich testified under oath that

1 better scope out Giant Eagle and Rite Aid? It
2 wouldn't cause you to do that, would it?

3 MS. KNIGHT: Objection to form.

4 A. That's totally outside of the
5 previous question. I just wouldn't come to make
6 that conclusion. It's such a limited amount of
7 facts why a doctor would say, don't fill them
8 across the street. Obviously maybe something
9 occurred and he directed them somewhere else, or he
10 already had a prearranged agreement with Overholts.

11 So just that broad statement, I can't
12 draw any conclusions from that.

13 Q. (BY MR. LIVINGSTON:) Are you aware
14 that the three agents all testified that all of the
15 defendants, to their knowledge and information,
16 were always in compliance with the Ohio Board of
17 Pharmacy regulations, including their many SOM
18 regulation and their corresponding duty
19 obligations, are you aware of that? Did you factor
20 that into your analysis?

21 A. I did not read their depositions and
22 I am not aware of that testimony.

23 Q. So the plaintiffs' attorneys did not
24 suggest to you that you should read those
25 depositions?

1 MS. KNIGHT: Object to form.

2 A. They don't suggest what to read or
3 what not to read. I -- I request documents to draw
4 my opinion.

5 My experience in dealings with boards
6 of pharmacies and the types of inspections they
7 conduct are more at a pharmacy level and typically
8 don't look at the same type of issues that I look
9 at.

10 Q. (BY MR. LIVINGSTON:) So are you
11 telling us that you didn't think it was important,
12 before you issued your opinion that these
13 pharmacies substantially contributed to the opioid
14 crisis in these two counties, it wasn't important
15 for you to look at what the Ohio Board of Pharmacy
16 agents had to say about whether those pharmacies
17 were acting lawfully or unlawfully?

18 MS. KNIGHT: Objection to form.

19 A. I don't qualify it as important or to
20 be unimportant. It is just something I didn't look
21 at in formulating my opinion.

22 Q. (BY MR. LIVINGSTON:) Well, we know
23 it wasn't important enough to be included on your
24 Schedule I, correct, as something that you
25 reviewed?

1 A. I did not review those documents,
2 sir.

3 MR. LIVINGSTON: I think we can take
4 a break.

5 MS. KNIGHT: Thank you.

6 THE VIDEOGRAPHER: The time is now
7 11:05 a.m. We're off the record.

8 MR. LIVINGSTON: Ten minutes.

9 (Whereupon, a break was had from
10 10:05 a.m. until 11:18 a.m. EDT)

11 THE VIDEOGRAPHER: The time is now
12 approximately 11:18 a.m. We're on the record.

13 MR. LIVINGSTON: I have still a
14 number of questions that I would like to ask this
15 witness. But as a matter of courtesy, I'm going to
16 now turn it over to my colleagues so that they can
17 get their questions in before the end of the day,
18 and then I will reserve my rights when they're
19 done, if there's time left, which I believe there
20 will be, to finish my questioning.

21

22 EXAMINATION BY MS. SWIFT:

23 Q. Mr. Rafalski, this is Kate Swift.
24 Can you hear me okay?

25 A. I can hear you, ma'am.

1 of conduct. It's just they failed it -- they
2 failed in the suspicious order monitoring system
3 and maintenance of effective controls.

4 So I have no intentions of coming in
5 and saying they're hypothetically thirty-three
6 percent responsible.

7 Q. Or any other level of responsibility?

8 A. Correct.

9 Q. Quantified?

10 A. Correct. It's just a failure as I
11 pointed out in my report.

12 Q. You're not connecting any failure
13 that you identify in your report to a level of
14 contribution to an opioids crisis in Lake or
15 Trumbull County, correct?

16 MS. KNIGHT: Object to form.

17 A. Well, I'm saying there's a
18 contribution. I am just not putting a figure on
19 it.

20 Q. (BY MS. SWIFT:) You can't quantify
21 the contribution; is that fair?

22 A. I did not try to do that, that's
23 correct.

24 Q. And you can't do it; is that fair?

25 MS. KNIGHT: Object to form.

1 A. Yeah, I think that would be outside
2 of my expertise other than just doing the raw
3 numbers. That would be a correct statement.

4 Q. (BY MS. SWIFT:) Right. We talked a
5 little bit about the Overholts Pharmacy that
6 received -- well, let's go back to the chart and
7 look at it. You can see the Overholts Pharmacy
8 received a hundred and seventy-six million MME,
9 compared to that biggest Walgreens on the list, the
10 one at 804 West Market which received about
11 forty-eight million MME, right, sir?

12 A. So now I'm seeing like a multitude of
13 screens. Do you --

14 MS. KNIGHT: Yeah, I think we're
15 seeing your background, Kate.

16 MS. SWIFT: Got it.

17 MR. FULLER: But thank you for the
18 realtime, Kate.

19 MS. SWIFT: Mike, anytime.

20 A. Appreciate that.

21 Q. (BY MS. SWIFT:) I appreciate your
22 letting me know.

23 A. It's so small --

24 MS. KNIGHT: I thought it was my
25 screen or I would have spoken up sooner. I was

1 A. I do not.

2 Q. Paragraph 6 -- or, sorry, 86, tells
3 us -- you can see the last sentence says, "Patients
4 from Tennessee accounted for approximately 18.4
5 percent." Do you see that?

6 A. Do.

7 Q. And then it says, "Patients from Ohio
8 accounted for approximately 11.5 percent" of the
9 prescriptions we are talking about. Do you see
10 that?

11 A. I do. Now, is that -- is that -- and
12 this is specific for American Pain, correct?

13 Q. This is specific for American Pain.

14 A. Okay.

15 Q. You didn't conduct any analysis of
16 this pain clinic or any other in Florida for
17 purposes of your Lake and Trumbull report, right,
18 sir?

19 A. I did not.

20 Q. You haven't conducted any analysis of
21 any Florida pain clinic for any of your reports
22 that you have issued in the opioids litigation,
23 right, sir?

24 A. I have not provided an opinion or
25 done any analysis in Florida.

1 Q. You don't have any opinion about the
2 extent to which the doctors and pain clinics
3 described in this federal indictment contributed to
4 the opioids epidemic anywhere in America, correct,
5 sir?

6 A. Well, I have an opinion that they
7 contributed significantly, but I -- it would just
8 be through my experience of working in the DEA and
9 having knowledge of the migration of the pills.

10 But I didn't -- I did not offer an
11 opinion on that, yeah, an expert opinion on that,
12 I'm sorry.

13 Q. Do you know how many doctors wrote
14 prescriptions for opioids in Lake and Trumbull
15 County during the relevant time period, from 2006
16 to the present?

17 A. I do not.

18 Q. Do you know how many of those
19 prescriptions were illegitimate, meaning they
20 weren't for a legitimate medical purpose?

21 A. I do not.

22 Q. You don't have any opinion on how
23 many prescriptions filled by one of the pharmacies
24 in this case were diverted?

25 A. So a part of -- so in forming my

1 expert opinion, I wasn't asked to review any
2 materials, documents or information related to
3 that, so I don't offer an opinion on that.

4 Q. You have no idea if any prescriptions
5 filled by a Walgreens pharmacy were diverted; is
6 that fair, because you didn't look?

7 A. I did not review prescriptions for --
8 specific prescriptions at any Walgreens, so I guess
9 that would be generally a correct statement.

10 Q. Do you know how many prescriptions
11 filled by any of the other pharmacies in Lake and
12 Trumbull were diverted after they were filled?

13 A. I do not.

14 Q. That is true, whether we are talking
15 about somebody taking a prescription bottle from a
16 friend's medicine cabinet or any other form of
17 diversion, you don't have any idea what those
18 numbers are?

19 A. No. I wasn't asked to provide an
20 opinion on that, so I don't have any information to
21 form an opinion on that or to --

22 Q. And you are not --

23 A. -- or to provide you with any numbers
24 or any direct knowledge of that.

25 Q. You are not aware of any pills that

1 Q. Yes.

2 A. No, I did not.

3 Q. Did you ever visit a pharmacy in Lake
4 or Trumbull County for purposes of preparing your
5 report?

6 A. I did not.

7 Q. And you never did the kind of
8 investigation you recommended to Mr. Crowley at
9 Purdue, correct?

10 A. That would be a much earlier time
11 frame, but, no, I did not go and sit and do any
12 observations at a Walgreens, that is a correct
13 statement.

14 Q. Or any other pharmacy in Lake or
15 Trumbull County, right, sir?

16 A. That's correct.

17 Q. You don't have any idea how many of
18 your flagged orders went to fill legitimate
19 prescriptions, right, sir?

20 A. Well, my flagged orders were flagged
21 for a specific reason. So it didn't make a
22 determination of what was diverted or what was not
23 diverted, but just my opinion is, based on the lack
24 of the due diligence on the first flagged order,
25 that more likely than not that those flagged orders

1 So how do you think Rite Aid's
2 pharmacies got oxycodone?

3 A. I'm not saying they have oxycodone.
4 If I understood your question, you asked about the
5 obligations, correct?

6 Q. On the pharmacy entities, correct.

7 A. Well, I think corporately there's
8 some responsibility for Rite Aid because they're a
9 chain facility, they have chain pharmacies, and
10 they're purchasing Schedule II products from an
11 outside vendor, but they're well aware of what
12 their pharmacies are purchasing.

13 So under the maintenance of effective
14 controls, I believe they have some responsibility
15 to monitor those drugs also.

16 Q. So let's take a look -- let's break
17 that down a little bit more. So we're going to go
18 within your report to Page 46. So we're going
19 to -- I think this is what you're referring to, if
20 I'm not mistaken, as an example. Tell me when
21 you're there.

22 A. Talking about the charts?

23 Q. Yep, talking about the charts. So
24 let's look at the first one there for Lake County
25 on Page 46, and this is under your methodology A.

1 Q. Your report references seven
2 suspicious order methodologies, some of which were
3 utilized by one or more of the defendants, correct?

4 A. That is a correct statement.

5 Q. Walmart did not utilize any of those
6 seven methodologies, right?

7 A. That is correct.

8 Q. And you agree that a distributor did
9 not need to use one of those seven methodologies to
10 have a sufficient suspicious order monitoring
11 program, correct?

12 A. Yeah. A distributor could have
13 designed one different from one of the
14 methodologies and potentially be effective.

15 Q. And, in fact, you think it would be
16 wrong for the DEA, for example, to suggest to
17 Walmart that it should have used one of those seven
18 methodologies, correct?

19 A. As part of my training as a diversion
20 investigator, it would have been wrong for me to
21 advocate the use of any specific system.

22 Q. Including the seven that you have in
23 your report, correct?

24 A. That would be any. That would be
25 correct. That would be encompassed to any.

1 from relying on employee experience to fulfill
2 their regulatory obligations, correct?

3 A. In certain -- in certain
4 circumstances, I believe that it is possible to
5 have a manual system. Depending on the type of
6 activity and the volume, it may not be sufficient.
7 But at the same time, the regulation requires that
8 you design and operate. And I'm not sure when you
9 have no policies, no procedures, no documentation,
10 that that is a design, outside of just it appears
11 to me kind of everybody telling everybody what to
12 do. It is difficult for me to say that that would
13 be in compliance with the regulation.

14 MS. FUMERTON: I move to strike that
15 as nonresponsive, so I will ask my question again.

16 Q. (BY MS. FUMERTON:) The Controlled
17 Substance Act and the regulations promulgated under
18 it do not prohibit registrants from relying on
19 employee experience to fulfill the regulatory
20 obligations, correct?

21 MS. KNIGHT: You can answer.

22 A. You will have to repeat that. That
23 is a different question, I believe.

24 Q. (BY MS. FUMERTON:) I read it
25 verbatim, but I will read it again.

1 You agree that the Controlled
2 Substances Act and the regulations promulgated
3 under it do not prohibit registrants from relying
4 on employee experience to fulfill their regulatory
5 obligations, correct?

6 MS. KNIGHT: Asked and answered.

7 A. I don't think the regulation speaks
8 specifically to that. I believe earlier we were
9 discussing a manual system. That is what I was
10 responding to earlier.

11 Q. (BY MS. FUMERTON:) And a manual
12 system is not prohibited either, correct?

13 A. It is not what? I'm sorry.

14 Q. Prohibited, correct?

15 A. A manual system is not as long as it
16 is sufficient to meet the needs of the registrant.

17 Q. You also mentioned the twenty bottle
18 limit that Walmart instituted for oxy 30 in 2012;
19 do you recall that?

20 A. I do.

21 Q. Sorry. 2012. I said it right. Do
22 you know why Walmart implemented that policy?

23 A. Yeah, I recall seeing an email. It
24 was in response to concerns about diversion of
25 oxycodone 30 in West Virginia and Florida.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

MDL NO. 2804

CASE NO. 17-md-2804

Hon. Dan A. Polster

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

TRACK THREE CASES

VOLUME II

REMOTE VIDEO DEPOSITION OF

JAMES RAFALSKI

June 11, 2021

REPORTED BY: Laura H. Nichols

Certified Realtime Reporter,

Registered Professional

Reporter and Notary Public

1 report, did you?

2 MS. KNIGHT: Objection to form.

3 A. I did not.

4 Q. (BY MR. LIVINGSTON:) You also didn't
5 factor into your analysis the effect that any
6 internet pharmacies had on the opioid crisis in
7 Lake and Trumbull County, correct?

8 A. That is correct.

9 Q. And that is despite the fact that you
10 knew from your time with the DEA that a major
11 contributor to the opioid crisis was internet
12 pharmacies, correct?

13 A. I am well aware of the effect of the
14 internet pharmacies. I don't know how it is
15 relevant to Lake and Trumbull County unless you are
16 indicating that maybe some of the residents there
17 were utilizing ordering those prescriptions online.
18 I'm not aware of any internet pharmacies that were
19 located in Lake and Trumbull County during the time
20 period of my review.

21 Q. Who said an internet pharmacy had to
22 be located physically in the county? Isn't that
23 the whole point, that you can just order on the
24 internet and have the drugs delivered to you?

25 A. That is the point.

1 Q. Okay.

2 A. So that is why I made that -- that's
3 why I gave that reply, because there would be no
4 way for me to know what residents of those two
5 counties ordered from the internet, other than if
6 there was -- in doing my review, there was never
7 any material that would provide me with that
8 information.

9 Q. But you are not suggesting that Lake
10 and Trumbull County residents didn't have the
11 internet available to them during the relevant
12 period, are you?

13 A. No. I think what I'm indicating,
14 there's no way I would know that they utilized the
15 internet to order internet opioid prescriptions and
16 have it delivered to those specific counties. That
17 information wouldn't be available to me.

18 Q. When you were with the Detroit office
19 of the DEA, was Detroit considered a major drug
20 supplier via drug gangs to neighboring states?

21 MS. KNIGHT: Objection to form.

22 A. Early in my career, I believe that
23 would be a correct statement.

24 Q. (BY MR. LIVINGSTON:) When you say
25 "early in your career," what do you -- what do you

1 mean by that? What time period are you talking
2 about?

3 A. I would say 2004. And it would have
4 been declining sometime prior to 2010. Maybe the
5 first three or four years I think there was quite a
6 bit of migration to a couple of different states.

7 Q. Well, one of those states was Ohio,
8 correct?

9 A. Ohio primarily only because it was a
10 bordering. But the actual illicit distribution in
11 my investigations, what I was aware was
12 predominantly it was mainly to Kentucky and then
13 secondly to Tennessee.

14 Q. Well, were you aware that a lot of
15 these Detroit-located drug gangs would pay elderly
16 citizens to get opioid scripts filled in -- at
17 Detroit pharmacies right down the street from your
18 office and then travel on Greyhound buses and
19 rented cars to Lake and Trumbull County to sell
20 those drugs there because they could get more per
21 pill than they could in Detroit? Were you aware of
22 that problem?

23 MS. KNIGHT: Objection to form.

24 A. I did not work any cases that
25 involved Lake and Trumbull County, and I did not

1 have any discussions from any investigators in that
2 region of the country. All of my cases had links
3 to, as I stated earlier, Kentucky and Tennessee.

4 I was aware that there was some
5 bouncing back and forth across the state borders
6 because the maps or the PMP programs didn't link
7 between each state. But I'm not aware of any case
8 that was worked out of the Detroit office that was
9 specifically tied to those two counties.

10 Q. (BY MR. LIVINGSTON:) Well, one thing
11 for sure we know from reading your report is that
12 you did not take into consideration the impact that
13 drug gangs had on selling illegitimately obtained
14 opioid scripts in Lake and Trumbull County,
15 correct?

16 A. No. My report, Mr. Livingston,
17 focuses on the distribution from the distributor
18 down to the pharmacy. My analysis doesn't focus on
19 the illicit conduct outside of that action.

20 Q. Okay. And -- well, you also didn't
21 review any of the law enforcement depositions that
22 were taken in this case in which testimony was
23 given that Detroit was a major supplier of
24 illegally obtained opioid pills to Lake and
25 Trumbull County, correct?

1 that have occurred where they are published on the
2 Federal Register or on the DEA website in regards
3 to pharmacies and their corresponding
4 responsibility. So I think there's plenty of
5 information available.

6 Have they specifically sent a list
7 out of red flags? I'm not aware of that.

8 Q. You didn't do any analysis to
9 determine to what extent the defendant pharmacists
10 in Lake and Trumbull County properly discharged
11 their duty to exercise their corresponding
12 responsibility?

13 A. I did not.

14 Q. And you did not endeavor to try to
15 determine whether any suspicious order at the
16 distribution level with respect to any of the
17 defendant pharmacies ultimately was used to fill an
18 illegitimate or not legitimate prescription,
19 correct?

20 A. That was not part of my analysis, no,
21 sir.

22 Q. Turn to Exhibit 2, your report,
23 Schedule I.

24 MS. KNIGHT: So Mr. Livingston, I
25 believe that is the -- I don't know what was wrong

1 A. That's correct.

2 MS. KNIGHT: Objection to form.

3 Q. (BY MR. LIVINGSTON:) And unlike
4 Mr. Colosimo and the other folks at the DEA
5 Pittsburgh office who inspected Giant Eagle's
6 facilities, you never actually physically inspected
7 either HBC or GERX; is that correct?

8 A. I never was physically present at
9 either of those locations, sir.

10 Q. Did you ever ask plaintiffs' counsel
11 for that opportunity?

12 A. To go there and inspect them?

13 Q. Yes.

14 A. I did not.

15 Q. Did they ever tell you that that was
16 an option, that under the Federal Rules, a party
17 can request and obtain the right to physically
18 inspect the other parties' facilities?

19 A. They did not tell me that. I am not
20 aware of that, sir.

21 Q. Now that you are aware of it, is that
22 something that you wish you had had the opportunity
23 to do before you rendered your opinions in this
24 matter?

25 A. Well, I think anything that I could

1 never kept records to be able to accurately answer
2 that, and I don't want to guess.

3 Q. And did you ever find that a
4 distributor's SOMS system that you inspected was in
5 compliance?

6 A. I believe there were some, yes.

7 Q. Okay. And what kind of threshold
8 system did they have?

9 A. Without disclosing the registrant,
10 one that I recall, because I had concerns going in,
11 was a manual system. And I actually found that to
12 be compliant, but it was based on a business
13 activity and the abilities and knowledge of the
14 employees.

15 I can recall a couple of smaller
16 companies that had compliance systems. I can also
17 recall some that did not. But off the top of my
18 head, I didn't really keep records or I don't have
19 a recollection specifically of the different
20 companies and what they had and didn't have.

21 Q. Without disclosing the name of the
22 registrant, the one that was a manual system, can
23 you tell us what was the nature of the business?
24 You said based on business activity. What did you
25 mean by that?

1 A. They were unique. They distributed
2 to dispensing doctors and specific kinds of -- like
3 dentists operating at clinics, and there were some
4 distributions I had concern with, but going onsite
5 and having a discussion with the compliance people
6 and the owner, I was -- I believed that they were
7 compliant in the knowledge of their registrants and
8 what they were dispensing in their business
9 activities. But it was -- the scope of their
10 business wasn't as large as a distributor like, for
11 example, Giant Eagle.

12 Q. My next question is, how many
13 customers, different customers, just roughly,
14 fifty, a hundred, a thousand, ten thousand?

15 A. Not thousands. I don't specifically
16 recall. I don't want to guess on that. I don't
17 believe it was even over a hundred. I believe it
18 was under a hundred, but I don't remember
19 specifically how many. It wasn't a large
20 distribution because it was a unique type of
21 business.

22 Q. Do you know how many pharmacies Giant
23 Eagle has in Ohio?

24 A. Just in the two counties overall, I
25 have seen a document about that, but I don't recall

1 aware if there were increases. It was a system
2 that I didn't find any faults with on that
3 particular inspection. I don't know moving forward
4 if it changed, but --

5 Q. All right. So you are aware that
6 Giant Eagle never received a letter of admonition,
7 correct?

8 A. I believe that is an accurate
9 statement, yes, sir.

10 Q. There was never any kind of
11 administrative action of any kind ever taken
12 against Giant Eagle for violating any DEA
13 regulations, correct?

14 A. Not that I am aware of.

15 Q. And Giant Eagle never was penalized
16 or entered into any kind of memorandum of
17 understanding for any violation of any DEA
18 regulations, correct?

19 A. That's correct.

20 Q. And you at least know -- you would at
21 least acknowledge that Giant Eagle was found to be
22 in full compliance at the conclusion of every
23 inspection that I mentioned to you earlier?

24 MS. KNIGHT: Objection to form.

25 A. I'm not sure that I reviewed every

1 inspection, the results, but I'm not going to
2 dispute your comment. But I don't have personal
3 knowledge of that.

4 Q. (BY MR. LIVINGSTON:) Are you saying
5 that, in the preparation of your opinion regarding
6 whether Giant Eagle's SOMS system was complying
7 with DEA regulations, you didn't think it was
8 material for you to consider, at least review and
9 consider the outcome of the inspection report,
10 inspections that were done by your DEA colleagues?

11 MS. KNIGHT: Objection to form.

12 A. I wouldn't say it wasn't important,
13 but I didn't put a high value on it only because in
14 my experience with the cases I have worked,
15 generally there would be clean inspections during
16 the time frame where I took action, in regarding,
17 specifically, Masters and Mallinckrodt.

18 Q. Well, you identify in your report
19 some instances where our co-defendants may have had
20 some minor violations of DEA regulations, correct?
21 You identify those in your report, correct?

22 MS. KNIGHT: Object to form.

23 A. Yes, sir.

24 Q. (BY MR. LIVINGSTON:) Okay. But in
25 your report, you don't mention that Giant Eagle had

1 Q. Do you see that we have just sort of
2 highlighted sort of the ultimate conclusion of the
3 reports and which inspections each one of these DEA
4 inspectors was involved with?

5 You see in 2009 when Mr. Colosimo did
6 the preregistration inspection for HBC and he
7 approved HBC's facility for a Schedule 3 license,
8 correct?

9 MS. KNIGHT: Objection to form.

10 A. It doesn't give all of those details.
11 And that is what your cheat sheet says, but I would
12 like to read the report where it says deemed
13 adequate, the security system to see specifically
14 what it says. But I acknowledge that your chart
15 says that.

16 Q. All right. Well, like I said, I kind
17 of suspected we probably would have to go back. We
18 will do that.

19 Just when you get to 2013, Mr. Conlon
20 concludes "no discrepancies with respect to
21 recordkeeping or security. Both recordkeeping and
22 security are in full compliance with..."

23 And when you do -- when the DEA does
24 these cyclic investigations, one of the major
25 things that they look at is the SOMS system,

1 correct, that is part of the security and
2 recordkeeping regulations?

3 A. Well, it is part of being -- doing
4 the onsite inspection. I don't know that it is
5 more important than any other section, but it is
6 something that they should review and comment on.

7 Q. Right. And Mr. -- I want to ask you,
8 remember we talked yesterday about how the
9 regulation refers to requiring registrants to be in
10 substantial compliance with the security
11 regulations; we went over that?

12 A. Yes, sir.

13 Q. And here we have a finding that Giant
14 Eagle was not substantially in compliance but
15 rather in full compliance, correct?

16 A. If that is what the statement of Mr.
17 Sousa says, then I agree that is what that
18 statement says.

19 Q. Okay. And in 2014, Mr. Sousa reaches
20 the same conclusion. He says "No discrepancies
21 with respect to recordkeeping or security. Both
22 recordkeeping and security are in full compliance."
23 Do you see that?

24 MS. KNIGHT: Object to form.

25 A. I do see that statement. But to say

1 recordkeeping and security are in full compliance,
2 it is a pretty broad statement without looking at
3 the report.

4 Q. (BY MR. LIVINGSTON:) Yes.

5 A. Not that I need to read them all, but
6 I wouldn't disagree that the report may say that.
7 Maybe in summary at the beginning, I am guessing.

8 Q. And when you go -- and your opinion
9 that is in your report is that from 2009, when HBC
10 first was granted a license for Schedule 3 drugs,
11 until hydrocodone was reclassified in 2014, during
12 that entire period of time, Giant Eagle was not
13 even in substantial compliance; it wasn't in
14 compliance at all, right?

15 A. In regards to their SOMS system,
16 that's correct.

17 Q. In other words, you disagree with the
18 conclusions reached by all of these DEA agents,
19 correct?

20 MS. KNIGHT: Object to the form.

21 A. Well, that is why I would like to
22 review the documents to ensure that they even
23 inquired about those things in their investigation.
24 It is not a mandate that they be required. So I
25 would like to see what description they had and

1 what awareness they had of the system. But I am in
2 disagreement if it says full compliance with
3 security, I do not disagree -- I do not agree with
4 that statement.

5 Q. (BY MR. LIVINGSTON:) So you publish
6 your report in April, which contains all of your
7 final opinions for this case, and now we are taking
8 your deposition in June. And you haven't taken the
9 time to review any of these inspection reports,
10 correct?

11 MS. KNIGHT: Objection to the form.

12 A. That's correct.

13 Q. (BY MR. LIVINGSTON:) Well, I guess
14 now is as good a time as any to finally look at
15 these reports. Let's go to Exhibit 34.

16 (GE Exhibit 34 was marked for
17 identification.)

18 Q. (BY MR. LIVINGSTON:) Page, at the
19 top, we will go to Page 9.

20 MS. KNIGHT: Just a moment. Sorry,
21 Mr. Livingston. He is getting there.

22 A. Go ahead.

23 Q. (BY MR. LIVINGSTON:) Okay. You see
24 this is a report by Mr. Colosimo regarding the
25 approval of HBC's request for a Schedule 3 license

1 substantial amount of time. I didn't keep a
2 specific amount of time. I know the total time I
3 wrote -- went -- spent on the report. I didn't
4 keep specific records for each of the companies.
5 So, no, I am not going to guess or ballpark it.

6 Q. All right. And then it says that
7 they had a meeting with management. You didn't
8 meet with Giant Eagle's management, did you?

9 A. I did not.

10 Q. Okay. Let's go down to the last
11 paragraph on this page. It says, "HBC was approved
12 as a distributor of List 1 chemicals on August 27,
13 1997, and was assigned DEA Registration Number.
14 The subject firm was the subject of in-depth cyclic
15 investigations in 2002, 2004 and 2008."

16 Now, you see that this report is
17 looking retrospectively at prior inspections of the
18 facility, correct?

19 MS. KNIGHT: Objection to form.

20 A. Yes. And that statement is specific
21 to a List 1 chemical.

22 Q. (BY MR. LIVINGSTON:) Right. Right.
23 Yeah, I wasn't suggesting otherwise. And that was
24 a common practice for you and other DEA inspectors
25 that in these reports, you would look -- you would

1 include what the outcome was of prior inspections,
2 correct?

3 A. Generally speaking, yes. I am not
4 sure that it would -- that it would cross over to
5 do other business activities, but that is just the
6 style of this writer.

7 Q. And then the next sentence says, "No
8 violations were uncovered during these
9 investigations. HBC was approved as a distributor
10 of controlled substances in October of 2009." Do
11 you see that?

12 A. I do.

13 Q. Okay. So again this is like probably
14 the, you would agree, the first cyclic inspection
15 of the HBC facility after it obtained, you know,
16 its Schedule 3 license, correct?

17 MS. KNIGHT: Object to the form.

18 A. By looking at the date and you
19 producing no other document, yes.

20 Q. (BY MR. LIVINGSTON:) All right.
21 Would you go to Page 33028 or Number 13 at the top?

22 A. Okay.

23 Q. It says, "After a thorough review and
24 analysis of the required records, it was determined
25 that all of the controlled substances were

1 So you see that Mr. Rogos is advising
2 and describing to the DEA inspectors that Giant
3 Eagle had a manual system at the time for
4 identifying suspicious orders in compliance with
5 1301.74(b).

6 MS. KNIGHT: Objection to form.

7 A. This statement that you highlighted
8 here, I would agree that it is manual and it only
9 identifies orders of unusual high orders. I don't
10 know what "high" means unless it means by size. It
11 does not say any compliance with pattern or
12 frequency. And then the last statement is -- I am
13 concerned by what issue is going to be brought to
14 the attention of Mr. Carlson and Ms. Remas.

15 Q. (BY MR. LIVINGSTON:) Yeah, we are
16 going to get there in a second.

17 A. Okay.

18 Q. Before we do -- and you yourself have
19 approved or at least found a manual system, a
20 manual SOM system to be in compliance with the SOM
21 regulation, correct?

22 A. Based on the business activity and
23 the scope of the that registrant, that is a correct
24 statement.

25 Q. Okay. Lets go to the next page of